

REMARKS

I. Status of the Claims

In response to a restriction requirement, applicants elected to prosecute claims 1 and 3, *i.e.*, the Group I claims. Thus, claims 1 and 3 have been examined and stand rejected under 35 U.S.C. §102 and 35 U.S.C. §112, second paragraph. The basis for the rejections, and applicants' response thereto, are set out in detail below.

II. Rejection Under 35 U.S.C. §112, Second Paragraph

The examiner has rejected claims 1 and 3 as lacking proper "Markush" format. Applicant traverse the rejection, but have provided a clarifying amendment that is believed to obviate the rejection.

III. Rejections Under 35 U.S.C. §102

Claims 1 and 3 are rejected as lacking novelty over three different references, each of which is said to disclose, embedded within a much larger polypeptide, the amino acid sequence of SEQ ID NO:27. Applicants traverse the rejection.

First, applicants submit that the situations presented by *In re Best* and *In re Fitzgerald* are not applicable here. In both cases, *compositions* were being claimed in terms of *functional* characteristics, and the issue was whether the prior art *methods* inherently provided products with those same *functional* characteristics. Here, there is no functional claiming, and similarly no question that the composition of matter is distinct from the prior art in a *structural* sense – the prior art contains long polypeptides and the claimed invention provides much shorter peptides.

The sequences clearly are distinct, and thus the fact situations of *Best* and *Fitzgerald* are not at all instructive.

To amplify on the point made above, each piece of cited art describes **polypeptides**: Mahoney *et al.* discloses a polypeptide of 152 residues; Bagella *et al.* discloses a polypeptide of 160 residues; and Merluzzi *et al.* discloses a polypeptide of 160 residues. These molecules are not clearly are not peptides – they are polypeptides. However, applicants have attempted to clarify the claimed invention by defining the peptides more specifically, *i.e.*, by inserting into the claims an “upper length” for the peptides of no more than 50 residues. Even though the claims still use “comprising” language, they are “open-ended” only to the extent that they may exceed the length of the specified SEQ ID NOs, but they cannot exceed 50 residues in length. Thus, it is believed that the subject matter as now claimed cannot be read as identical to that disclosed in the cited references.

Reconsideration and withdrawal of the rejections is, therefore, respectfully requested.

IV. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned at (512) 536-3184 with any questions, comments or suggestions relating to the referenced patent application.



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Date: November 25, 2002

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Steven L. Highlander".

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APPENDIX A: MARKED UP COPY OF CLAIMS

1. (Amended) An isolated antimicrobial peptide [comprising] of not more than 50 residues,
the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH₂ (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH₂ (SEQ ID NO: 16),
RRIIRKIIHIIK-NH₂ (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
RGLRRLGRKIAHGVKKYGPTVLRIRIA-NH₂ (SEQ ID NO. 27), [or] and
KNLRRIIRKIIHIIKKYGPTILRIIRIG-NH₂ (SEQ ID NO. 28).

3. (Amended) A pharmaceutical composition [wherein said composition comprises the] comprising an antimicrobial peptide of not more than 50 residues, the peptide comprising [the] an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIIK-NH₂ (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH₂ (SEQ ID NO: 16),
RRIIRKIIHIIK-NH₂ (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
RGLRRLGRKIAHGVKKYGPTVLRRIIRIA-NH₂ (SEQ ID NO. 27), [or] and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH₂ (SEQ ID NO. 28)[; and]₂
formulated in a pharmaceutically acceptable carrier.

APPENDIX B: CLEAN COPY OF PENDING CLAIMS (UNOFFICIAL)

1. An isolated antimicrobial peptide of not more than 50 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 11),
LRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRIIRKIIHIK-NH₂ (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH₂ (SEQ ID NO: 16),
RRIIRKIIHIK-NH₂ (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
RGLRRLGRKIAHGVKKYGPTVLRIRIA-NH₂ (SEQ ID NO. 27), and
KNLRRIIRKIIHIIKKYGPTILRIIRIIG-NH₂ (SEQ ID NO. 28).

3. A pharmaceutical composition comprising an antimicrobial peptide of not more than 50 residues, the peptide comprising an amino acid sequence selected from the group consisting of:

KNLRRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 1),
KNIRRIIRKIIHIIKKYG-NH₂ (SEQ ID NO: 6),
KNIRRIIRKIIHIIKKYG (SEQ ID NO: 7),
KNLRRRIIRKIIHIIKKYG (SEQ ID NO: 8),
NLRRIIRKIIHIIKKY (SEQ ID NO 9),
NIRRIIRKIIHIIKKY (SEQ ID NO: 10),
LRRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 11),
LRRRIIRKIIHIIKK (SEQ ID NO: 12),
IRRIIRKIIHIIKK-NH₂ (SEQ ID NO: 13),
IRRIIRKIIHIIKK (SEQ ID NO: 14),
LRRRIIRKIIHIIK-NH₂ (SEQ ID NO: 15),
RRIIRKIIHIIKK-NH₂ (SEQ ID NO: 16),
RRIIRKIIHIIK-NH₂ (SEQ ID NO: 17),
GLRKRLRKFRNKIKEKLKKIG (SEQ ID NO: 19),
KRLRKFRNKIKEKLKKIG (SEQ ID NO: 20),
RKRLRKFRNKIKEKLKKIGQKI (SEQ ID NO: 21),
LRKFRNKIKEKLKKIGQKI (SEQ ID NO: 22),
LRKFRNKIKEKLKKIGQKIQG (SEQ ID NO: 23),
RKFRNKIKEKLKKIG (SEQ ID NO: 24),
KIKEKLKKIGQKIQG (SEQ ID NO: 25),
KIKEKLKKIGQKIQGLL (SEQ ID NO: 26),
RGLRRLGRKIAHGVKKYGPTVLRRIIRIA-NH₂ (SEQ ID NO. 27), and
KNLRRRIIRKIIHIIKKYGPTILRIIRIIG-NH₂ (SEQ ID NO. 28),
formulated in a pharmaceutically acceptable carrier.